

Application No.: 10/695,295
Amdt dated: December 26, 2006
Reply to Office action of August 25, 2006

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Remarks/Arguments

Claims 1, 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravener et al., U.S. Pat. No. 5,360,417; claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein, et al., U.S. Pat. No 5,460,616. Claim 2 is rejected under 35 U.S.C. 103 as unpatentable over Gravener in view of Mollenauer et al., U.S. Pat. No. 5,514,109. Claim 1 has been amended by incorporating claim 3 into claim 1 and claim 3 canceled; no new matter has been added. Claims 1-10 are discussed below.

Claims 1, 2, 4 and 5: Claim 1 is an independent claim, with claims 2, 4 and 5 depending therefrom. Claim 1 provides, emphasis added:

A surgical valve having an axis extending between a proximal and a distal end, comprising:

a housing including a proximal housing portion and a distal housing portion cooperating with the proximal housing portion to define a gel cavity;

a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics;

a proximal guide tube extending axially proximally from the proximal housing portion;

the proximal guide tube facilitating insertion of a surgical instrument into the seal material;

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a distal guide tube extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal, wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion.

MPEP § 2131 provides:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In *re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)."

As noted above, claim 1 recites a proximal guide tube having "exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion." The Office action points to the device in *Gravener*, identifying the proximal guide tube 22 with an exterior portion 22 extending

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proximally of the proximal housing portion 26 and an interior portion 34 extending distally of the proximal housing portion 26. (Office action, page 4, lines 4-7).

Applicants respectfully disagree. First, Gravener identifies 22 as a "proximal opening" rather than as a tube, consistent with the figures depicting the Gravener device. See, e.g., col. 5, lines 29-31, and FIG. 3. Similarly, Gravener refers to 34 as "the inner wall 34 of the neck 26" (col. 4, lines 50-53), so clearly wall 34 of neck 26 cannot be extending distally of 26, as asserted in the Office action. Indeed, as shown in FIG. 3, among others, of Gravener, there is no proximal guide tube in Gravener's device unless one considers the housing (Gravener's proximal end portion 16) to be the equivalent of a guide tube, as the Office action seems to assert. By contrast, claim 1 of the present invention recites a seal having a guide tube which extends from the housing, both proximally and distally. Applicants respectfully submit that the Office action fails to identify any comparable structure in Gravener.

Similarly, the Office action points to the device in Weinstein, suggesting that Weinstein includes a proximal guide tube 16 including an exterior portion 18 extending proximally of the proximal housing portion PH and an interior portion (Applicants note that the Office action identifies structure 20 as the interior portion) extending distally of the proximal housing portion. (Office action, page 4, lines 4-7). Weinstein defines 16 as a cap having "a snap fit flange 18" and defining "an aperture 20." Col. 2, 58-60. Again, the Office action apparently takes the position that the housing (or cap and snap flange, using Weinstein's terminology) is equivalent to a guide tube extending distally and proximally from a housing portion but Applicants' respectfully submit that this is

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unsupported by Weinstein. Compare, for example, Applicants' FIG. 7, showing a proximal housing portion 74a with an associated guide tube, having a proximally extending lead-in portion 123 and a distally extending distal portion 127 with Weinstein's FIGs. 2 and 3, and the difference is apparent.

As the devices in Gravener and Weinstein do not, to Applicants' knowledge, teach a proximal guide tube having "exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion, they cannot anticipate claim 1 nor any of the claims depending therefrom. Accordingly, Applicants respectfully request that the §102 rejection of claims 1-5 be withdrawn.

Moreover, Applicants respectfully request that the §103 rejection of claim 2 be withdrawn. As noted above, Gravener fails to teach a proximal guide tube having exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion. The Office action points to no teaching or suggestion in Mollenauer of such a guide tube. Accordingly, the Office action fails to make a prima facie case of obviousness.

Claims 6-9: Claim 6 is an independent claim, with claims 7-9 depending therefrom. Claim 6 provides, emphasis added:

A surgical valve, comprising:

a first housing portion defining a gel cavity;

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a seal material including a gel and having a node and an axial channel;
a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and
a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state.

According to the Office action, Gravener teaches "a node (32)" Applicants respectfully disagree that Gravener's structure 32 discloses a node in a seal material. According to Gravener, "the proximal end portion 16 further includes a plurality of **splines 32** attached to an inner wall 34 and preferably integrally molded as part of inner wall 34. Alternatively, splines 32 may be insert molded and may include rigid members below the surface of inner wall 34, e.g., metallic strips or the like. The splines 32 extend in a generally longitudinal direction to assist in the insertion of an instrument into the neck portion 26 by reducing friction and drag forces associated therewith. Further, the splines 32 substantially prevent unwanted contact between the instrument and the inner wall 34 of the neck 26 that may injure or puncture the body 12." Col. 4, lines 41-53. The Office action points to no teaching in Gravener that these splines are part of the sealing material; indeed, Gravener describes the sealing material (gel 42) as injected

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into a cavity 40, which is shown in FIGs. 6 and 7, for example, as distinct from the splines 32. (Col. 4, lines 56-66.)

Similarly, the Office action points to Weinstein's tricuspid valve 27 as a node in the sealing material and further asserts an axial channel cavity in the sealing material, although no reference is provided. Applicants must again respectfully disagree. Weinstein describes a sheath 12 filled with a jelly and having tricuspid valves on either end. (Col. 3, lines 1-7). No reference is made to an axial channel cavity, nor to a node in the sealing material (indeed, a valve designed to open upon application of pressure by an instrument penetrating the sheath would not be likely to facilitate placing an axial channel in a closed state even were such a channel contemplated in the Weinstein device).

Applicant respectfully disagrees that either Gravener's splines or Weinstein's tricuspid valve anticipates Applicants' seal material node. Accordingly, Applicants respectfully request that the §102 rejection of claims 6-9 be withdrawn.

Claim 10: Claim 10 provides:

A surgical valve adapted to form a seal around a surgical instrument extending through the valve, comprising:

- a first housing portion;
- a second housing portion engaging the first housing portion

and defining with the first housing portion a gel cavity having a volume;

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a gel disposed within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument; and

means for moving the second housing portion axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

According to the Office action, both Gravener and Weinstein teach "a means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel material on the instrument . . . (G col. 4, line 64, W col 1 line 47)." Office action page 5, lines 3-9.

Col. 4, line 64 of Gravener reads: "The gel 42 fills cavity 40 and provides longitudinal and radial pressure about the aperture 14 (FIG. 3)." As shown in FIGs. 3-7 of Gravener and described in the accompanying text, "the elongated substantially cylindrical distal portion 18 is folded onto itself and pulled proximally in the direction of the arrows. The distal edge 20 is affixed to the proximal wall plate 24 creating a cavity 40 by conventional techniques such as adhesives or heat sealing. Inlet port 36 is provided for injection of a gel 42, e.g., silicone, or like substance into cavity 40 while outlet port 38 provides a conduit for eliminating air from cavity 40." Even assuming strictly for the sake of argument that the "folding onto itself" movement can be

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considered axial movement, it is apparent that this motion has no effect on the gel pressure as the gel is not even added until after this folding motion creates the cavity that will ultimately receive the gel. Nothing described are illustrated here teaches a means for moving the second housing portion axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve, as recited in claim 10.

Likewise, col.1, line 47 of Weinstein provides: "Preferably, the fluid present in the fluid-filled chamber is a gel, for example, a silicone gel or petroleum jelly." Applicants are unable to locate, nor does the Office action provide, any reference in Weinstein describing means for moving the second housing portion axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve, as recited in claim 10. Accordingly, Applicants respectfully request that the §102 rejection of claim 10 be withdrawn.

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Based on foregoing remarks, Applicants respectfully submit that all pending claims are in condition for allowance and earnestly solicit a notice thereof. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the Application.

Sincerely

APPLIED MEDICAL RESOURCES

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